STANDARD OPERATING PROCEDURE – MANAGEMENT OF TEMPERATURE EXCURSIONS WITH COMIRNATY® COVID-19 VACCINE

INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccination		
OBJECTIVE	- To provide guidance for the management of temperature excursions with Comirnaty® - COVID-19 Vaccine.		
SCOPE	- Monitoring Safety and Efficacy of Comirnaty® COVID-19 Vaccine.		
COMPILED BY		**ORIGINAL DATE:**	
AUTHORISED BY			
DEFINITIONS	**Cold chain medicines** means medicines that must be stored within the cold chain within a specified temperature range from the time of manufacture through transportation and delivery to health establishments (vaccination sites) until the administration thereof. **Vaccines** means biological medicines that must be stored under specific temperature conditions, in accordance with the manufacturer's recommendations. **Vaccinator** means a designated health care provider trained, competent and acting within their scope of practice who administers a COVID-19 vaccine to a client. **Vaccine Champion** means a person who is designated to manage the vaccine supply chain at a place where vaccines are administered. Such person may be a pharmacist, pharmacist's assistant or nurse and may also function as the vaccination site manager, or as a vaccinator. **Vaccine controller** means a pharmacist or pharmacist's assistant, or other health care professional designated to manage the storage and supply of vaccines, the distribution of vaccines to primary vaccination sites, outreach sites and/or the supply of vaccines to mobile teams (where applicable) and the updating of data on the Stock Visibility System (SVS).		
ABBREVIATIONS	-		
POLICIES, REFERENCES, SOURCE MATERIAL	- Provincial Drug Supply Management Policy/ Prescript (As applicable) - Pharmacy Act 53 of 1974 - Medicines and Related Substances Act 101 of 1965 - Good Pharmacy Practice rules published in terms of the Pharmacy Act 53 of 1974 - Cold chain and Immunisation Operations Manual of 2015 - National Environmental Management: Waste Act 59 of 2008 - National Environmental Management Act 107 of 1998 - Hazardous Substances Act 15 of 1973		
RELATED SOPs	- Receiving of vaccines - Distribution of vaccines - Storage of vaccines		
PRINCIPLES	1. Regular monitoring of temperatures is mandatory for the minimisation and management of temperature excursions.		

	2. The vaccine champion and supervisory pharmacist must be informed, and appropriate steps taken to manage the situation immediately. 3. Actions must comply with manufacturer's documented advice and/or WHO recommendations. 4. An incident report and root cause analysis investigation must be completed with the relevant managers/vaccine champion being informed.
FUNCTIONAL ROLES AND RESPONSIBILITIES	- Vaccine controller - Vaccinator - Vaccine Champion - Supervising pharmacist - Pharmacist's assistant (basic) - Pharmacist's assistant (post-basic) - Professional nurse (responsible for medicine supply management)
TOOLS/ MATERIALS/ EQUIPMENT	- Vaccine Thermometers
SAFETY WARNINGS	- N/A
MONITORING AND EVALUATION	
RECORD KEEPING	Incident report of cold chain failure should be kept

1.1. PROCEDURE:

No	PROCEDURE	RESPONSIBLE
This Standard Operating Procedure (SOP) consists of the following sections: 1. Identification of Affected Batches 2. Managing Temperature Excursions While Vaccine is Frozen 3. Managing Temperature Excursions While Vaccine is in 2°C to 8°C in Closed Vials 4. Managing Temperature Excursions in Open Vials 5. Reporting of Temperature Excursions		
1	**Identification of Affected Batches**	
1.1	If temperature excursions should occur: Identify the affected batches and numbers of vials.	Vaccine Controller
1.2	Move vaccines to alternative refrigerator/freezer. If removal not possible; close the door of refrigerator/freezer.	Vaccine Controller

1.3	All vaccines suspected to have been exposed to unsuitable temperatures should be labelled as “DO NOT USE, UNTIL FURTHER NOTICE”	Vaccine Controller
1.4	Write date and time when noncompliance to cold chain was identified.	Vaccine Controller
2	**Managing Temperature Excursions While Vaccine is Frozen**	
2.1	Check the temperature records of freezer and temperature monitoring devices.	Vaccine Controller
2.2	The vials are stable up to 24 hours from -3°C to 2°C.	Vaccine Controller
3	**Managing Temperature Excursions While Vaccine is in 2°C to 8°C in Closed Vials**	
3.1	Check the temperature records of refrigerator and temperature monitoring devices.	Vaccine Controller
3.2	Unopened vials are stable for up to a total of 4 hours when stored at temperatures from 8°C to 30°C; this includes the 2 hours at up to 30°C if thawed at room temperature.	Vaccine Controller
4	**Managing Temperature Excursions in Open Vials**	
4.1	Check drug accountability logs.	Vaccine Controller
4.2	Vaccine must be discarded after 6 hours after first puncture of the vial.	Vaccine Controller
5	**Reporting of Temperature Excursions**	
5.1	Create a facility report indicating the number of vials suspected/affected and the cause	Vaccine Controller
5.2	Forward a written report to the Pharmacy Manager at primary site and District Pharmacist specifying reasons why the storage conditions were not adhered to.	Supervisory pharmacist
5.3	Undertake a root cause analysis investigating reasons for temperature excursion.	Supervisory pharmacist
5.4	Confirm whether vaccine can be used after reviewing temperature records. If advised that products are safe for use, then mark as “Use First” and date	Supervisory pharmacist
5.5	If vaccines are confirmed to have been damaged: - Complete the relevant waste disposal documentation. - Vaccine vials should be discarded in biohazardous waste or a medical waste container, such as used for expired pharmaceutical stock. - Remove or deface the label on each vaccine vial with a black permanent marker	Supervisory pharmacist
5.6	Develop and implement quality improvement plans to reduce risk of temperature excursions.	Supervisory pharmacist and Vaccine Controller

ANNEXURES	None

2. REVISION DATA

Revision No	Pages	Revision Details	Date	Approved

TRAINING REQUIRED

- **Training to be conducted post SOP sign-off and prior to the effective date as per above**
- **Training to be provided to relevant responsible parties after each SOP revision**

Trainees	Type of training

3. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			